DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTES OF HEALTH NATIONAL CENTER FOR RESEARCH RESOURCES

NATIONAL ADVISORY RESEARCH RESOURCES COUNCIL MINUTES OF MEETING JANUARY 22, 2004

The National Advisory Research Resources Council convened for its 126th session at 8:30 a.m. on Thursday, January 22, 2004, in Conference Room 10, Building 31. Dr. Judith L. Vaitukaitis, Director, National Center for Research Resources (NCRR), National Institutes of Health (NIH), presided as Chair. The meeting was open to the public until 1:30 p.m., at which time it was closed to the public for the review, discussion, and evaluation of grant applications as provided in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code, and Section 10(d) of Public Law 92-463.

COUNCIL MEMBERS PRESENT

Dr. Stephen W. Barthold

Dr. Robert J. Beall

Dr. Wah Chiu

Dr. Randall E. Dalton

Dr. Robert J. Desnick

Dr. Machi F. Dilworth

Liaison Member, NSF

Dr. Mark H. Ellisman

Dr. Catherine C. Fenselau

Dr. James G. Fox

Dr. Eon Nigel Harris

Dr. Roland F. Hirsch

Liaison Member, DOE

Dr. Joan S. Hunt

Dr. Gwen A. Jacobs

Dr. John E. Maupin, Jr.

Dr. Thomas G. McGuire

Dr. William R. Morton

Dr. Diana S. Natalicio

Dr. Monte Westerfield

COUNCIL MEMBERS ABSENT

Ms. Catherine D. Bertram, J.D.

Dr. Paul G. Ramsey

Dr. William W. King

SPECIAL INVITED GUESTS FOR OPEN SESSION

- Dr. Delwood C. Collins, Associate Vice President for Research and Graduate Studies, University of Kentucky Medical Center
- Dr. Nancy H. Hopkins, Professor of Biology, Department of Biology, Center for Cancer Research, Massachusetts Institute of Technology
- Dr. Keith G. Mansfield, Associate Professor of Pathology, New England Primate Research Center, Harvard Medical School

Dr. Eric A. Nofzinger, Associate Professor of Psychiatry, Western Psychiatric Institute and Clinic, University of Pittsburgh at Pittsburgh

STAFF OF OTHER NIH COMPONENTS

Dr. Margaret Snyder, OD/OER/OSA Dr. John Bowers, CSR

OTHERS PRESENT

Ms. Vicki Contie, Equals Three Communications, Bethesda, MD
 Mr. Stephen Heinig, Senior Staff Associate, Division of Biomedical and Health Sciences Research, Association of American Medical Colleges, Washington, DC
 Ms. Nancy Moy, SRI International, Menlo Park, CA

OPEN SESSION

I. Call to Order: Dr. Judith Vaitukaitis, Director, NCRR

Dr. Vaitukaitis welcomed Council members and guests to the 126th meeting of the National Advisory Research Resources Council. She announced that the following Council members would not be present: Ms. Catherine Bertram, Dr. Paul Ramsey, and Dr. William King. Four new members were recently appointed to the Council by Tommy Thompson, Secretary, Department of Health and Human Services (DHHS). These new members (listed below) will attend the May 2004 Council meeting.

- Dr. Kenneth G. Cornetta, Joe C. Christian Professor and Chairman, Department of Medical and Molecular Genetics, Indiana University
- Dr. Cynthia Keppel, Director, Hampton University Center for Advanced Medical Instrumentation, Hampton University
- Ms. Sheila Cohen Zimmet, J.D., Director, Research Assurance and Compliance, Georgetown University
- Dr. Stuart Zola, Director, Yerkes National Primate Research Center, Emory University

Dr. Vaitukaitis acknowledged the invaluable service of the following retiring Council members: Ms. Catherine Bertram, Dr. Robert Desnick, Dr. William Morton, and Dr. Diana Natalicio.

II. Consideration of Minutes: Dr. Judith L. Vaitukaitis, Director, NCRR

The minutes of the Council meeting held on September 11, 2003, were approved as written.

III. Future Meeting Dates: Dr. Judith Vaitukaitis, Director, NCRR

The next Council meeting will be held on Thursday, May 20, 2004.

IV. Personnel Update: Dr. Judith Vaitukaitis, Director, NCRR

DHHS Personnel

No changes to report.

NIH Personnel

Dr. Norka Ruiz Bravo was appointed as the new Deputy Director for Extramural Research at NIH. Dr. Bravo has been with the NIH since 1990, first working as a Scientific Review Administrator at the National Institute of General Medical Sciences (NIGMS). Prior to this appointment, Dr. Bravo held the position of Associate Director for Extramural Activities at NIGMS.

Dr. Jeremy M. Berg was appointed as the new Director of the NIGMS by NIH Director Elias Zerhouni in November 2003. Prior to this appointment, Dr. Berg served as Director of the Institute for Basic Biomedical Sciences and Professor and Director of the Department of Biophysics and Biophysical Chemistry at the Johns Hopkins University School of Medicine in Baltimore.

Dr. Faye Calhoun was recently named Deputy Director of the National Institute on Alcohol Abuse and Alcoholism (NIAAA). Dr. Calhoun joined NIAAA in 1995 as Associate Director of the Office of Collaborative Research. Prior to joining NIAAA, she served as Deputy Chief of the Referral and Review Branch in the Division of Research Grants, currently the Center for Scientific Review.

Dr. Gerald T. Keusch announced, in November 2003, his plans to step down as Director of the Fogarty International Center (FIC) and NIH Associate Director for International Research. Dr. Keusch has been named Assistant Provost for Global Health at the Boston University Medical Campus and Associate Dean for Global Health at Boston University School of Public Health. Dr. Sharon Hrynkow, who has served as FIC Deputy Director since 2000, began serving as Acting Director of the Center in January 2004.

NCRR Personnel

Dr. Peter T. Highnam joined the NCRR staff as Senior Advisor to the Director of NCRR in November 2003. Dr. Highnam is responsible for advising the Director on Information Technology issues. Prior to this appointment, Dr. Highnam served as a Program Manager for the Defense Advanced Research Projects Agency (DARPA).

Dr. Mohan Viswanathan was selected as the new Deputy Director of NCRR's Office of Review in November 2003. Prior to joining NCRR as a Scientific Review Administrator in July 2001, Dr. Viswanathan worked at Children's National Medical Center where he studied the vascular effects of melatonin.

Dr. Carol A. Bean joined the NCRR staff as a Health Science Administrator in the Division for Biomedical Technology Research and Research Resources in September 2003. Previously, she was a Program Officer at the National Library of Medicine.

Ms. Barbara N. Perrone retired from her position as Director of NCRR's Office of Science Policy & Public Liaison in January 2004, after 38 years of service to NIH. She guided NCRR's scientific programs for the past 27 years.

Dr. John D. Strandberg retired from NCRR in January 2004. Since January 1999, he has directed the Division of Comparative Medicine. Prior to joining NCRR, Dr. Strandberg was a Professor at the Johns Hopkins University School of Medicine where he directed the Division of Comparative Medicine.

Dr. Jerry A. Robinson retired from NCRR in January 2004. He joined NCRR in 1995, and for more than eight years, Dr. Robinson has been the Director of the National Primate Research Centers and the AIDS Animal Models Programs in the Division of Comparative Medicine.

V. Legislative and Budget Updates: Dr. Judith Vaitukaitis, Director, NCRR

Dr. Vaitukaitis reported on the 2004 NCRR Appropriation:

The President's budget request had included \$1,053,926,000 for NCRR, with no funding designated for NCRR's extramural construction program. In June 2003, the Senate Labor/HHS/Education Appropriations bill was passed, providing NCRR \$1,186,483,000, with specific funding levels for General Clinical Research Centers (GCRCs), the Institutional Development Award (IDeA) Program, and restoration of extramural construction funds.

In July 2003, the House of Representatives passed the Labor/HHS/ Education Appropriations bill, providing NCRR with an appropriation of \$1,053,926,000, the same amount as the President's request.

A conference bill, providing \$1,186,183,000 to NCRR—but reducing its budget by \$7,125,000 due to across the board budget reductions for all NIH Institutes and Centers—was passed by the House of Representatives as part of a consolidated omnibus appropriations bill early in December. The omnibus appropriations bill will be considered by the Senate when they convene on January 20, 2004.

VI. Zebrafish as a Model for Studying Early Vertebrate Development: Dr. Nancy Hopkins, Professor of Biology, Massachusetts Institute of Technology (MIT)

Dr. Hopkins discussed the zebrafish as an excellent animal model for studying early vertebrate development. The fish's fertilized egg originates from a single cell to a functional animal in just five days, and its transparent embryo allows scientists to rapidly analyze the different phases of its life. Dr. Hopkins explained how her research of creating transgenic zebrafish may help to explain genes involved in human development and disease, since some of their genes are homologous to humans. She uses an approach called insertional mutagenesis. This technique uses a mouse retrovirus to induce mutations in the fish embryo. By doing this, researchers can observe the different deformities and deduce which changes in the genes affect the development of a particular organ. Dr. Hopkins has successfully identified 25 percent of the genes required for zebrafish development.

Dr. Hopkins' research team has identified mutant zebrafish with kidney defects due to mutated genes. In fact, two of the genes sequenced are known to cause cystic kidney disease in humans. Other examples of genes Dr. Hopkins and her collaborators are researching involve the development of the jaw, liver, myeloid cell, and the stem cell.

Through the various screenings of different lines of zebrafish, Dr. Hopkins and her research team have detected mutated ribosomal proteins, which phenotypically created tumors on the zebrafish. These tumors are called malignant peripheral nerve sheath tumors (MPNSTs). Dr. Hopkins and her team have determined that these MPNSTs are a defective form of the tumor suppressor gene in zebrafish.

Through her ongoing screening of zebrafish, Dr. Hopkins will continue to make strides in determining what genes are needed to develop organs of a vertebrate embryo.

VII. Strategic Planning Forum - Summary & Recommendations

Every five years, NCRR develops a Strategic Plan to anticipate the research resource needs of the NIH-supported biomedical community. To prepare the Strategic Plan for 2004-2008, NCRR asked scientists around the country to identify emerging scientific trends and make recommendations concerning research resources and technologies that will be needed in the future. The information provided by researchers served as a framework for discussions at a planning forum held on September 10-11, 2003. The recommendations and discussions then were synthesized into a document that outlines the various strategic planning goals along with corresponding objectives. The presenters listed below summarized the goals and objectives for Council's review and discussion:

Dr. Wah Chiu, Alvin Romansky Professor of Biochemistry Department of Biochemistry and Cell Biology, Baylor College of Medicine Discussion of goals related to "Informatics and Computational Biology" and "Emerging Technologies and Instrumentation"

Dr. Monte Westerfield, Professor of Biology

Institute of Neuroscience, University of Oregon

Discussion of goals related to "Nonhuman Models for Biomedical Research"

Dr. Thomas G. McGuire, Professor

Department of Health Care Policy, Harvard Medical School

Discussion of goals related to "Clinical Research Resources and Networks"

Dr. Stephen W. Barthold, Professor of Pathology, Microbiology and Immunology; Director, Center for Comparative Medicine

School of Veterinary Medicine, University of California

Discussion of goals related to "Research Capacity Building" and "Training and Education"

The publication, NCRR's 2004-2008 Strategic Plan: Challenges and Critical Choices, will be distributed in the coming weeks.

VIII. Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities Annual Report: Dr. Delwood C. Collins, Associate Vice President for Research and Graduate Studies, University of Kentucky Medical Center

Dr. Collins reported on the activities of the Scientific and Technical Review Board (STRB) on Biomedical and Behavioral Research Facilities. The STRB continued its annual review of applications for the Extramural Research Facilities Construction Program (C06), as well as review of Animal Facilities Improvement (G20) applications through FY 2003.

The STRB reviewed 122 C06 applications with a recommended funding level of \$355 million. Forty awards were funded at a total of \$120 million. Included in the funding was a \$5 million award to the congressionally mandated Chimpanzee Sanctuary. No FY 2003 data were available for the G20 program.

IX. Report on the Biomedical Informatics Research Network (BIRN): Dr. Michael T. Marron, Director, Division for Biomedical Technology Research and Research Resources, NCRR

Dr. Marron reported that the pace of biomedical data generation has increased so dramatically that the enormous volume of information has become a new problem for biomedical scientists. In order to move from data collection to scientific discoveries, scientists need new systems to organize, analyze, and share data. The objective of the BIRN is to help biomedical researchers overcome the flood of data by building a stable, high-performance network, creating federated databases, developing software, and aiding researchers in regulatory compliance.

The BIRN initiative is in the process of expanding to 13 active sites and adding a functional MRI component that will focus on schizophrenia. The initiative started with supplemental awards to existing centers to expedite the formation of the network, but

funding for the program will use more cooperative agreements in the future. The funding mechanism is being changed to enhance the ability to coordinate activities between testbeds and improve feedback from NIH and the scientific community. The BIRN has matured rapidly in the two years since its inception and is on the verge of a major expansion. In March 2004, a meeting will be held to demonstrate the achievements of the BIRN to program staff from across NIH. The purpose of the meeting is to generate new initiatives and share the benefits of the BIRN program throughout the research community.

X. Report on the Biomedical Informatics Expert Panel (BIEP): Dr. Peter T. Highnam, Senior Advisor, Office of the Director, NCRR

Dr. Highnam reported that, in January 2004, NCRR convened the first meeting of the Biomedical Informatics Expert Panel (BIEP). The BIEP is composed of experts in areas of biomedical research and informatics. The purpose of the BIEP is to guide NCRR staff in developing wide-ranging research tools, including tools required for accessing virtual laboratories, scaleable computing, tools for collaboratories and data sharing, data management tools, and a state-of-the-art bioinformatics toolbox. The BIEP was formed in direct response to the challenges represented by the increasing complexity of research and the marked increase in the volume of data generated. The informatics infrastructure must be in place to ensure that research progress will not be hampered.

In addition to extensive discussions, the Panel heard presentations in three areas. The BIRN was described in depth, and future plans were covered by Dr. Mark Ellisman (University of California at San Diego), Dr. Greg McCarthy (Duke University), and Dr. Michael Marron (NCRR). The NCRR strategic investments to increase the computer network connectivity into and within six northwestern IDeA states in the NCRR Biomedical Research Infrastructure Network (BRIN) program were covered by Dr. Gwen Jacobs (Montana State), Dr. Ron Johnson (University of Washington), and Dr. Sidney McNairy (NCRR). A discussion on current NCRR plans to provide substantial improvements in informatics infrastructure to support clinical research was summarized by Dr. Elaine Collier (NCRR) and Dr. Peter Highnam (NCRR).

XI. Report and Recommendations from the Research Centers in Minority Institutions (RCMI) Principal Investigators Meeting: Dr. John E. Maupin, President, Meharry College

The RCMI Principal Investigators and Program Directors meet annually to discuss progress, opportunities, and challenges faced by the RCMI Program. Dr. Maupin reported that, at the November 14-15, 2003 meeting, the following recommendations were made: 1.) appoint an expert team to perform a needs assessment to implement networking plans at RCMI sites; 2.) provide the resources necessary to accelerate the establishment of the RCMI Clinical Research Network; 3.) re-issue the Clinical Research Education and Career Development Request for Applications, and allow sufficient time to ensure that RCMI sites will be competitive for Clinical Research Curriculum (K30) Awards; 4.) increase collaboration between the Division for Clinical Research Resources and the Division of

Research Infrastructure to transition RCMI Clinical Research Centers to GCRCs; 5.) encourage all NCRR grantees to take full advantage of the resources available at the Bioethics Center of Tuskegee University; 6.) develop an internal steering committee at each RCMI grantee institution to develop a strategic plan for coordination of NIH-supported programs; 7.) expand the Comprehensive Centers on Health Disparities to include schools of pharmacy and dentistry; 8.) develop plans to facilitate wider involvement of the RCMI grantee institutions with NIH Roadmap initiatives; 9.) provide additional support for Web-based resources that will facilitate collaborations; and 10.) provide continued support to upgrade and maintain animal facilities at RCMI institutions.

XII. Council Operating Procedures: Dr. Louise Ramm, Deputy Director, NCRR

Dr. Ramm reported four minor modifications to the Council Operating Procedures: 1.) the use of the electronic Council book has eliminated the need to distribute a complete set of signed summary statements to voting Council members prior to the Council meeting; 2.) voting members will no longer have electronic access to <u>all</u> summary statements to be reviewed by Council. Members will only have access to summary statements that do not create conflicts of interest; 3.) expedited review will hereafter be referred to as "early en bloc concurrence;" 4.) the phrase "during the time of the meeting of the initial review group and that of Council" was stricken from page nine of the Council Operating Procedures.

The Council Operating Procedures were accepted as modified.

CLOSED SESSION

This portion of the Council meeting was closed to the public in accordance with the determination that it was concerned with matters exempt from mandatory disclosure under Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

Council members discussed procedures and policies regarding voting and confidentiality of application materials, Committee discussions, and recommendations. Members absented themselves from the meeting during discussion of and voting on applications from their own institutions, or other applications in which there was a potential conflict of interest, real or apparent. Members were asked to sign a statement to that effect.

XIII. Application Review

Council considered 420 applications in the total amount of \$189,580,542.

ADJOURNMENT

The Council adjourned at 3:00 p.m. on January 22, 2004.

CERTIFICATION

Attachment: Council Roster

We hereby certify that, to the best of our knowledge, the foregoing minutes and supplements are accurate and complete.	
Judith L. Vaitukaitis, M.D.	Date
Chair, National Advisory Research Resources Council and	
Director, National Center for Research Resources, NIH	
Louise E. Ramm, Ph.D.	 Date
Executive Secretary, National Advisory Research Resources Council and	
Deputy Director, National Center for Research Resources, NIH	
These minutes will be formally considered by the Council at its next meeting notations will be incorporated into the minutes of that meeting.	; corrections or

NOTE: Open Session materials are available from the Executive Secretary or the Committee Management Office, NCRR.